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UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

AHMAD ODEH, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. IMMUNOMEDICS, INC., et al., Defendants.	No. 2:18-cv-17645-MCA-ESK **(Consolidated)** CLASS ACTION

FIRST AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

INTRODUCTION AND OVERVIEW

1. Lead Plaintiffs Construction Industry and Laborers Joint Pension Trust and Boris Saljanin (together,"Plaintiffs") hereby bring this action on behalf of themselves and all persons or entities who purchased or otherwise acquired the common stock of Immunomedics, Inc. ("Immunomedics" or the "Company") between February 9, 2018 and January 17, 2019, inclusive (the "Class Period"), and were damaged thereby. Excluded from the Class, as defined below, are Defendants, present or former executive officers of Immunomedics and their immediate family members (as defined in 17 C.F.R. §229.404, Instructions (1)(a)(iii) and (1)(b)(ii)). Plaintiffs seek to recover damages caused by Defendants' violations of §§10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), and Rule 10b-5 promulgated thereunder.

2. Plaintiffs allege the following based on personal knowledge as to themselves and their own acts and upon information and belief as to all other matters. Plaintiffs' information and belief is based on, among other things, the independent investigation of their counsel, Robbins Geller Rudman & Dowd LLP and Block & Leviton LLP. This investigation included, but was not limited to, a review and analysis of: (i) Immunomedics' public filings with the U.S. Securities and Exchange Commission ("SEC"); (ii) transcripts of Immunomedics' public conference calls; (iii) Immunomedics' press releases; (iv) independent media reports regarding

Immunomedics; (v) economic analyses of Immunomedics' stock price movement and pricing and volume data; (vi) consultation with relevant experts; (vii) relevant regulatory communications, including those between the U.S. Food and Drug Administration ("FDA") and Immunomedics; and (viii) other publicly-available material and data identified herein.

3. Counsel's investigation of the facts underlying this action continues, and counsel further believes that relevant facts are known only by Defendants (and their agents) or are exclusively within their custody or control. Plaintiffs believe that additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

4. Immunomedics is a clinical-stage biopharmaceutical company that purports to develop monoclonal antibody-based products for the targeted treatment of cancer. Since its formation in 1982, the Company has not obtained FDA approval for any drug that it has developed. Prior to and throughout the Class Period, the Company's primary focus was to commercialize sacituzumab govitecan (referred to herein as "IMMU-132") as a third-line therapy for patients with metastatic triple-negative breast cancer ("mTNBC").

5. In February 2016, the FDA granted IMMU-132 "Breakthrough Therapy Designation" (which provides for expedited FDA review). However, investors started to criticize the Company for failing to aggressively capitalize on

this opportunity. For instance, in November 2016, the Company's largest shareholder, venBio Select Advisor LLC ("venBio"), complained in proxy materials that Immunomedics had failed to find a partner to assist the Company in obtaining FDA approval of IMMU-132, had been experiencing ongoing delays in ramping up IMMU-132 manufacturing, and otherwise lacked the world-class manufacturing facilities necessary to drive IMMU-132 to potential FDA approval.

6. In response to venBio's and other investors' concerns, in February 2017, Immunomedics announced that it had entered into a $2 billion licensing agreement with Seattle Genetics, Inc. ("Seattle Genetics"). Under the terms of the licensing agreement, Seattle Genetics would be responsible for conducting a Phase 3 clinical trial for IMMU-132 in patients with mTNBC and submitting the biologic license application ("BLA") to the FDA for review. Seattle Genetics would also be solely responsible for manufacturing and commercializing IMMU-132. venBio immediately objected to the licensing agreement, claiming that Immunomedics management was giving away the Company's "crown jewel" and asserting that the licensing transaction was really a sale of Immunomedics to Seattle Genetics on the cheap. After a heated proxy battle – and public lawsuit – venBio representatives succeeded in gaining four seats on the Immunomedics Board of Directors and ousting the Company's top executives, including its Chief Executive Officer ("CEO") and the Company's founder.

7. By late spring 2017, the newly constituted Board of Directors (which included defendants Dr. Behzad Aghazadeh, Scott Canute, Peter Barton Hutt, and Khalid Islam) informed investors that they – unlike Immunomedics' prior management – possessed the requisite expertise to establish the necessary manufacturing infrastructure for IMMU-132 for the specific purpose of obtaining FDA approval and launching the drug in the United States during 2018.

8. Between November 2017 and February 2018, Immunomedics announced the hiring of defendants Michael Pehl (as CEO) and Morris Rosenberg (as Chief Technology Officer) to further bolster the perceived expertise of the new management team and assure investors that Immunomedics would remain on track in delivering IMMU-132 to the market by the end of 2018.

9. On January 31, 2018, however, Defendants discovered that their Morris Plains, New Jersey manufacturing plant, where IMMU-132 would be commercially manufactured if approved by the FDA, suffered from a serious data integrity breach (hereinafter the "Data Integrity Breach"). The Data Integrity Breach was described by Immunomedics internally as involving Company personnel deliberately manipulating bioburden samples, deliberately misrepresenting test procedures in batch records and intentionally backdating batch records (including the dates of the analytical results). The Data Integrity Breach was a critical risk to FDA approval.

If the Company failed to demonstrate to the FDA that it had determined the scope of the Data Integrity Breach and remediated it, the FDA would not approve the BLA.

10. Public documents (made available after the Class Period) reveal Defendants' admissions that they were "immediately" made aware of the Data Integrity Breach upon its discovery in January 2018, and that due to its severity, it was "immediately" reported to the FDA. While Defendants also acknowledged that they concluded the Data Integrity Breach was of the "utmost concern" to them upon its discovery in January 2018, they still deliberately withheld from the FDA (on the basis of a purported attorney-client privilege) facts underlying the scope of the Data Integrity Breach and whether it was ever remediated.

11. After assuring investors that Immunomedics' new management team – comprised of each of the Individual Defendants (defined herein) in this case – was capable of establishing and managing a world-class manufacturing capability in support of IMMU-132, Defendants were clearly motivated to mislead investors throughout the Class Period regarding the status of the Morris Plains manufacturing facility and conceal the issues involving the Data Integrity Breach.

12. On February 8, 2018, for example, defendant Michael Pehl deliberately and falsely "***confirm[ed] that all critical work streams, including, for example, the previously discussed manufacturing validation runs, are yielding positive results***."

13. On the same day, defendant Morris Rosenberg described the Company's purported communications with the FDA concerning Immunomedics' manufacturing capabilities, saying the FDA "***[has] seen our whole manufacturing process***," but disclosed nothing about how the manufacturing process suffered from a serious Data Integrity Breach or that the FDA had been immediately notified of the Data Integrity Breach.

14. On February 22, 2018, defendant Michael Pehl spoke with analysts and investors about manufacturing process validation at the Morris Plains facility and Immunomedics' preparation of the facility for the highly anticipated FDA pre-approval inspection. But, again, Pehl said nothing about the Data Integrity Breach at the Morris Plains facility.

15. In June 2018, while the truth about the Data Integrity Breach was still unknown by the market, Immunomedics sold over 1.7 million shares of stock for net proceeds of $300 million pursuant to a Form S-3ASR and prospectus. Defendants Michael Pehl, Michael Garone, Behzad Aghazadeh, Scott Canute, Peter Barton Hutt and Khalid Islam each signed the S-3ASR. While the SEC filing warned the Company could suffer material adverse effects to its financial condition and results of operations ***if*** it suffered a security breach to its information systems, it failed to disclose that Immunomedics already suffered a serious Data Integrity Breach as a result of Immunomedics employees' deliberate and fraudulent conduct. At the time

these Pehl, Garone, Aghazedeh, Canute, Hutt and Islam signed the Form S-3ASR and directed the $300 million stock offering, they each had direct knowledge of the circumstances of the Data Integrity Breach.

16. Between August 6 and August 14, 2018, the FDA conducted an inspection of the Morris Plains facility. One key purpose of the inspection was to engage with Immunomedics concerning the status of the Data Integrity Breach. But each time the FDA asked Defendants for written proof regarding the scope of the Data Integrity Breach and whether the Company had resolved it, Defendants refused to provide it to the agency, claiming it was protected by attorney-client privilege.

17. On August 14, 2018, during the pre-approval inspection close-out meeting with Immunomedics senior executives, the FDA informed the Company that without written proof of the Company's verbal assertions concerning the scope of the Data Integrity Breach and Immunomedics' purported remediation of it, the agency could not make any assessment as to whether the Data Integrity Breach had been resolved. On August 14, 2018, moreover, the FDA issued a Form 483 to Immunomedics and Michael Pehl – an official report issued at the conclusion of an inspection if the investigators identify conditions that may constitute violations of relevant statutes – that again reiterated that the agency could not assess the Data Integrity Breach due to Immunomedics' refusal to provide written proof of

resolution. But even in the Company's September 4, 2018 final response to the Form 483, Defendants again refused to provide the FDA with the required proof.

18. On December 20, 2018, prior to the market open, equity analyst Dr. Elliot Favus, M.D. ("Favus") of Favus Institutional Research issued a report (the "Favus Report") that broadly disseminated the details of the August 14, 2018 Form 483 issued to Michael Pehl and Immunomedics. When the market opened, the Company's stock price immediately dropped from $17.64 to below $13.00 per share, causing investors millions of dollars in damages.

19. On December 20, 2018, in an effort to obfuscate the news about the Form 483 and temper the downward stock price pressure, Defendants immediately began issuing additional false and misleading statements to investors through friendly equity analysts. For instance:

- At 10:00 a.m. EST, Guggenheim Securities LLC ("Guggenheim") analysts stated: "We spoke with management who pointed out to us that this Form-483 was already received 4 months ago, this August, and the company believes it has addressed [the] manufacturing issues cited in the form."

- At 11:00 a.m. EST, Morgan Stanley analysts stated: "We spoke with mgt. . . . [The Company] believes they have communicated with the FDA about the issues prior to the 483 and have worked to remediate all the key issues. [The Company] further indicated that if these issues, including the 483, were material they would have issued a release highlighting the issues."

- At 11:30 a.m. EST, Wells Fargo Securities, LLC ("Wells Fargo") analysts stated: "We have spoken with management this morning regarding observations and understand that they occurred as part of a

pre-approval inspection in early August . . . and that the observations are 'old news' and a remediation has long been put in place."

- At 1:00 p.m. EST, Piper Jaffray analysts stated: "We spoke with IMMU which emphasized that some observations were flagged and discussed with the FDA well ahead of the inspection and that . . . IMMU feels that it is in a very good place."

- After the markets closed, a Jefferies analyst added: "[T]he company confirmed that it received the inspection reports in August of this year, and feel that it has addressed all of the issues raised during the inspection. While mgmt did not disclose specific content, they were outwardly confident that everything was adequately addressed, and further that they are confident in a positive decision by the FDA on or before the Jan PDUFA date."

Each of these statements, attributed to Immunomedics' management by key sell-side analysts, were materially misleading.[1] Defendants knew, but failed to disclose, that the FDA requested written proof of Data Integrity Breach resolution and Defendants refused to provide that to the agency. Defendants' misstatements succeeded in halting the downward pressure on Immunomedics stock price, which ***closed down $3.47*** per share for the day.

20. Then, on January 10, 2019, defendant Michael Pehl again deliberately deceived investors when he said the Company "***did take care of [the issues listed in the Form 483] very early***." One week later, after the close of the market on January 17, 2019, Immunomedics disclosed receipt of a Complete Response Letter ("CRL")

[1] Morgan Stanley, Jefferies and Wells Fargo were underwriters for Immunomedics' June 2018 $300 million common stock offering.

notifying the Company that the FDA had rejected approval of IMMU-132 due to unresolved manufacturing violations at the Morris Plains manufacturing facility. As a result, the Company's stock price fell to $13.31 per share, down 26% compared to the prior day's close of $18.09 per share, resulting in a market capitalization loss of approximately $1 billion.

JURISDICTION AND VENUE

21. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)), and Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5).

22. This Court has jurisdiction over this action pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1331.

23. Venue is properly laid in this District pursuant to 28 U.S.C. §1391(b) and (c). The acts and conduct complained of herein occurred in substantial part in this District.

24. In connection with the acts and conduct alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including the mails and telephonic communications and the facilities of the Nasdaq stock market.

PARTIES

Plaintiffs

25. Construction Industry and Laborers Joint Pension Trust ("Pension Trust"), based in Nevada, purchased Immunomedics common stock during the Class Period on the Nasdaq and was damaged thereby. *See* ECF No. 6-2, Ex. B. Pension Trust is a defined-benefit plan that manages approximately $385 million in assets for the benefit of approximately 5,100 participants (including retirees and beneficiaries).

26. Boris Saljanin, a resident of New York, purchased Immunomedics common stock during the Class Period on the Nasdaq and was damaged thereby. *See* ECF No. 11-2, Ex. B.

Defendants

27. Immunomedics is a Delaware corporation that describes itself as a clinical-stage biopharmaceutical company focusing on the development of antibody-based products for the treatment of cancer. During all relevant times, the Company stated that its "most advanced product candidate" was IMMU-132. The Company's principal offices are located at 300 The American Road, Morris Plains, NJ 07950. Since the Company was founded in 1982, it has incurred significant operating losses and, over the course of nearly 40 years, has not developed any drug that the FDA approved for marketing and sales in the United States. Immunomedics is a control

person of the Individual Defendants within the meaning of §20(a) of the Exchange Act.

28. Defendant Michael Pehl ("Pehl") served as the Company's CEO between December 7, 2017 and February 25, 2019. During that period, Pehl also served as a member of Immunomedics' Board of Directors. The Company's March 2, 2018 Proxy Statement described Pehl as having more than 20 years of experience in hematology and oncology and having launched multiple blockbuster drugs. Prior to being appointed CEO at Immunomedics, Pehl worked in several executive positions at Celgene Corporation ("Celgene"). Pehl was forced to resign from the Company on February 22, 2019, three weeks after the FDA sent a written communication to Immunomedics, which included a copy of the FDA's Establishment Inspection Report concerning, among other things, the Data Integrity Breach at the Morris Plains manufacturing facility.

29. Prior to and during the Class Period, Pehl was responsible for complying with the Company's Code of Ethics for the CEO and Senior Financial Officers (adopted by Immunomedics Board of Directors in 2003) ("Senior Officer Code of Ethics"). The Senior Officer Code of Ethics required Pehl to "[c]arefully review a draft of each" "financial press release or other public communications by the Company" and "SEC report and related documents for accuracy and completeness before each such report is filed with the SEC, with particular focus on

disclosures issues within his or her area of responsibility." The Senior Officer Code of Ethics warned that any "violation of this Code will subject a Senior Officer to disciplinary action, up to and including a discharge from the Company and, where appropriate, may subject the Senior Officer to civil liability and criminal prosecution." Pehl was also subject to the Company's External Communications Policy ("Communications Policy"). The Communications Policy stated that Pehl, together with the Company's Chief Financial Officer ("CFO") and Head of Investor Relations, were the only persons authorized by Immunomedics to speak on its behalf to the public. The purpose of the Communications Policy was to ensure clear guidelines "for . . . making disclosures of, material information to ensure all required disclosures are made accurately, timely and on a broadly disseminated basis as defined by SEC Regulation Fair Disclosure." The Communications Policy defined "[n]on-public communications with regulators, including the FDA" as a specific example of "[m]aterial [n]on-[p]ublic [i]nformation."

30. Pehl made or had authority over the content and dissemination of the false and misleading statements and omission set forth herein at ¶¶93-103, 106, 108-113, 115-120, and is liable for those false statements and omissions. Pehl is also a control person of Immunomedics within the meaning of §20(a) of the Exchange Act.

31. Defendant Usuma Malik ("Malik") served as the acting CFO of the Company during the Class Period. Prior to being appointed acting CFO in August

2018, Malik had served as the Company's Chief Business Officer since August 2017. Malik's appointment as acting CFO followed Michael Garone's August 23, 2018 resignation as CFO. Prior to working for Immunomedics, Malik served in various executive positions at Pfizer Inc., Booz & Co. and KPMG Consulting.

32. During the Class Period, Malik was responsible for complying with the Company's Senior Officer Code of Ethics. The Senior Officer Code of Ethics required Malik to "[c]arefully review a draft of each" "financial press release or other public communications by the Company" and "SEC report and related documents for accuracy and completeness before each such report is filed with the SEC, with particular focus on disclosures issues within his or her area of responsibility." The Senior Officer Code of Ethics warned that any "violation of this Code will subject a Senior Officer to disciplinary action, up to and including a discharge from the Company and, where appropriate, may subject the Senior Officer to civil liability and criminal prosecution." Malik was also subject to the Communications Policy. The Communications Policy stated that the CEO, Malik and Immunomedics' Head of Investor Relations were the only persons authorized by Immunomedics to speak on its behalf to investors and the public. The purpose of the Communications Policy was to ensure clear guidelines "for . . . making disclosures of, material information to ensure all required disclosures are made accurately, timely and on a broadly disseminated basis as defined by SEC Regulation Fair Disclosure." The

Communications Policy defined "[n]on-public communications with regulators, including the FDA" as a specific example of "[m]aterial [n]on-[p]ublic [i]nformation."

33. Malik made or had authority over the content and dissemination of the false and misleading statements and omission set forth herein at ¶¶109-113, 115-119, and is liable for those false statements and omissions. Malik is also a control person of Immunomedics within the meaning of §20(a) of the Exchange Act.

34. Defendant Michael Garone ("Garone") served as the Company's CFO from the start of the Class Period through his resignation on August 23, 2018, the same day he signed the Company's 2018 Form 10-K. Garone continued to serve as the Company's Vice President of Finance until he resigned from that position as well on December 24, 2018, four days after the publication of the Favus Report regarding Immunomedics' Form 483. Prior to working at the Company, Garone served in executive financial positions at several companies, including Emisphere Technologies, Inc., Australis, Ltd. and AT&T, Inc.

35. During the Class Period, Garone was responsible for complying with the Company's Senior Officer Code of Ethics. The Senior Officer Code of Ethics required Garone to "[c]arefully review a draft of each" "financial press release or other public communications by the Company" and "SEC report and related documents for accuracy and completeness before each such report is filed with the

SEC, with particular focus on disclosures issues within his or her area of responsibility." The Senior Officer Code of Ethics warned that any "violation of this Code will subject a Senior Officer to disciplinary action, up to and including a discharge from the Company and, where appropriate, may subject the Senior Officer to civil liability and criminal prosecution." Garone was also subject to the Communications Policy. The Communications Policy stated that the CEO, Garone (during the period he was CEO) and Immunomedics' Head of Investor Relations were the only persons authorized by Immunomedics to speak on its behalf to investors and the public. The purpose of the Communications Policy was to ensure clear guidelines "for . . . making disclosures of, material information to ensure all required disclosures are made accurately, timely and on a broadly disseminated basis as defined by SEC Regulation Fair Disclosure." The Communications Policy also defined "[n]on-public communications with regulators, including the FDA" as a specific example of "[m]aterial [n]on-[p]ublic [i]nformation."

36. Garone made or had authority over the content and dissemination of the false and misleading statements and omission set forth herein at ¶¶93, 97, 100, 102-103, 106, and is liable for those false statements and omissions. Garone is also a control person of Immunomedics within the meaning of §20(a) of the Exchange Act.

37. Defendant Morris Rosenberg ("Rosenberg") served as the Company's Chief Technology Officer ("CTO") throughout the Class Period. According to the

Company's February 28, 2018 press release announcing Rosenberg's January 2018 hiring, Rosenberg had "been a key consultant to Immunomedics for the past nine months, focusing on building an outstanding team and preparing for commercial launch [of IMMU-132], including a robust CMC package for BLA submission."

38. Rosenberg was also subject to the Communications Policy. According to the Communications Policy, Rosenberg could not speak on behalf of the Company "without the prior approval of the Company Spokespersons" (*i.e.*, the current CEO, CFO and Head of Investor Relations, among others). During the Class Period, Rosenberg made several public statements on behalf of the Company, as alleged at ¶¶95-96, 115-119. In accordance with the Communications Policy, defendants Pehl, Garone and Malik had to have approved Rosenberg to speak on the Company's behalf regarding, among other things, the status of the Morris Plains manufacturing facility during the Class Period. The purpose of the Communications Policy was to ensure clear guidelines "for . . . making disclosures of, material information to ensure all required disclosures are made accurately, timely and on a broadly disseminated basis as defined by SEC Regulation Fair Disclosure." The Communications Policy defined "[n]on-public communications with regulators, including the FDA" as a specific example of "[m]aterial [n]on-[p]ublic [i]nformation."

39. Rosenberg made or had authority over the content and dissemination of the false and misleading statements and omission set forth herein at ¶¶95-96, 115-

119, and is liable for those false statements and omissions. Rosenberg is also a control person of Immunomedics within the meaning of §20(a) of the Exchange Act.

40. Defendant Dr. Behzad Aghazadeh ("Aghazadeh") has been a member of Immunomedics' Board of Directors since March 2017. Throughout the Class Period, Aghazadeh was the Company's Executive Chairman of the Board of Directors. At all relevant times, Aghazadeh served as Managing Partner and Portfolio Manager of venBio. Between 2000 and 2006, Aghazadeh was in the healthcare practice at Booz Allen Hamilton Holding Corporation (now a unit of PricewaterhouseCoopers), and between 2006 and 2011 served as an analyst for Bernstein Value Equities and Sio Capital Management.

41. Aghazadeh made or had authority over the content and dissemination of the false and misleading statements and omission set forth herein at ¶¶102-103, 106, 115-119, and is liable for those false statements and omissions. Aghazadeh is also a control person of Immunomedics within the meaning of §20(a) of the Exchange Act.

42. Defendant Scott Canute ("Canute") has been a member of Immunomedics' Board of Directors since March 2017. Throughout the Class Period, Canute served on Immunomedics' Executive Committee, Audit Committee, Compensation Committee (Chair), Governance and Nominating Committee and Research & Development Committee. Between 2004 and 2007, Canute served as

the President of Global Manufacturing Operations at Eli Lilly and Company and between 2010 and 2011, as President of Global Manufacturing and Corporate Operations at Sanofi Genzyme.

43. Canute made or had authority over the content and dissemination of the false and misleading statements and omission set forth herein at ¶¶102-103, 106, 115-119, and is liable for those false statements and omissions. Canute is also a control person of Immunomedics within the meaning of §20(a) of the Exchange Act.

44. Defendant Peter Barton Hutt ("Hutt") has been a member of Immunomedics' Board of Directors since March 2017. Throughout the Class Period, Hutt served on Immunomedics' Executive Committee, Compensation Committee and Governance and Nominating Committee (Chair). Since 1975, Hutt has served as Senior Counsel of Covington & Burling LLP. Between 1971 and 1975, Hutt served as the FDA's Chief Counsel.

45. Hutt made or had authority over the content and dissemination of the false and misleading statements and omission set forth herein at ¶¶102-103, 106, 115-119, and is liable for those false statements and omissions. Hutt is also a control person of Immunomedics within the meaning of §20(a) of the Exchange Act.

46. Defendant Dr. Khalid Islam ("Islam") has been a member of Immunomedics' Board of Directors since March 2017. Throughout the Class Period, Islam served on Immunomedics Executive Committee (Chair), Audit

Committee (Chair), Compensation Committee, Governance and Nominating Committee and Research & Development Committee (Chair). Between 2009 and 2014, Islam served as the Chairman and CEO of Gentium S.p.A. and since 2014 served as the Managing Director of Life Sciences Management GmbH.

47. Islam made or had authority over the content and dissemination of the false and misleading statements and omission set forth herein at ¶¶102-103, 106, 115-119, and is liable for those false statements and omissions. Islam is also a control person of Immunomedics within the meaning of §20(a) of the Exchange Act.

48. Defendants Immunomedics, Pehl, Malik, Garone, Rosenberg, Aghazadeh, Canute, Hutt and Islam are collectively referred to herein as "Defendants."

49. Defendants Pehl, Malik, Garone, Rosenberg, Aghazadeh, Canute, Hutt and Islam are collectively referred to herein as the "Individual Defendants."

FACTUAL BACKGROUND

Metastatic Triple-Negative Breast Cancer – "mTNBC"

50. mTNBC is a serious disease. It includes about 12% of all breast cancer types. mTNBC is more aggressive than other forms of breast cancer. It is more likely to spread to other areas of the body, and there is a higher chance it will come back within the first three years after treatment. It is also more likely to be fatal

within the first five years. But once a patient passes those milestones, his or her odds of beating it are about the same as someone with any other type of breast cancer.

51. One of the distinguishing features of mTNBC is that it tests negative for three of the main things – the hormones estrogen and progesterone and a protein called HER2 – that drive other forms of cancer.

52. Because mTNBC is different than other forms of cancer in this way, it does not respond to some of the medications that work for these other types of cancer. And patients with mTNBC have a poorer short-term prognosis than other subtypes, in part because of this lack of targeted therapies for this cancer type. *See* Giampaolo Bianchini, Justin Balko, Ingrid Mayer, Melinda Sanders & Luca Gianni, *Triple-negative breast cancer: challenges and opportunities of a heterogeneous disease*, 13 Nature Rev. Clinical Oncology, 674-690 (May 17, 2016).

53. Therefore, new targeted treatment therapies are desperately needed to save lives.

Sacituzumab Govitecan or IMMU-132

54. Throughout the Class Period, Immunomedics' primary focus was the commercialization of IMMU-132, which was predominantly intended to be marketed for the treatment of patients with mTNBC who had received at least two prior therapies for metastatic disease. IMMU-132 was also touted as a possible product candidate in the treatment of other solid tumors and cancers.

55. IMMU-132 is an antibody-drug conjugate ("ADC"), which means it is made up of an antibody attached to an anticancer drug. IMMU-132 is designed to deliver a specified payload of chemotherapeutics directly to the tumor. The biologic product is believed to work by binding the antibody portion of the drug to the tumor(s), while the anticancer drug portion works to prevent the cancer cells from growing and/or spreading. ADCs have less toxicity than conventional chemotherapy, thereby reducing the total exposure of a patient to the debilitating side effects typically associated with therapeutic agents. This targeted treatment and lower toxic exposure is what makes ADCs unique.

56. As of 2018, if approved by the FDA, IMMU-132 would be the first ADC of its kind approved for use by patients with mTNBC. Given that Immunomedics had failed to obtain FDA approval of any drug candidate in the Company's near 40-year history, market participants were keenly focused on the regulatory pathway of IMMU-132, including the FDA's BLA pre-approval inspection of the Company's Morris Plains manufacturing facility.

57. Because of Immunomedics' history of suffering material operating losses since 1982, the Company had to obtain funding for research and development and operations from the private and public sale of equity and debt securities, in addition to relatively small amounts of revenue from licensing agreements for other drug compounds. Prior to the Class Period, Immunomedics made a strategic

decision to shift from merely developing potential new drug candidates to developing and commercializing therapeutic product candidates. As a result, Immunomedics' spending on research and development increased significantly, costing the Company $53.5 million in 2016, $51.8 million in 2017 and $99.3 million in 2018. This pattern of increased spending was a direct result of the Company's efforts to obtain FDA approval of IMMU-132 and establish a first-class manufacturing facility for the drug.

Immunomedics' Attempt to License IMMU-132 to Seattle Genetics

58. In February 2016, Immunomedics announced that the FDA had granted IMMU-132 Breakthrough Therapy Designation, which serves to speed up the development and FDA review of drugs that could represent an improvement over existing therapies. The FDA's Breakthrough Therapy Designation was a significant recognition that IMMU-132 had the potential to significantly improve the outcome for patients with mTNBC.

59. Investors became frustrated with Immunomedics' perceived failure to capitalize on the opportunity presented by the FDA's Breakthrough Therapy Designation. For instance, in 2016, investors believed that Immunomedics' management had failed to maintain sufficient funds to push IMMU-132 through a Phase 3 clinical program, and otherwise failed to find a competent partner to assist

in getting IMMU-132 approved by the FDA and in the hands of patients who could benefit from the drug.

60. In November 2016, Immunomedics' largest shareholder, venBio, filed materials with the SEC that described a number of Immunomedics' perceived failures with regard to the development and commercialization of IMMU-132. As a result, venBio nominated a majority slate of dissident director candidates and triggered a heated and protracted proxy fight. Among other things, venBio expressed the following concerns:

- In June 2016, the Company announced that it had been ejected from a meeting of the American Society of Clinical Oncology ("ASCO") because management had failed to adhere to a data embargo policy, meaning that it shared the data on the IMMU-132 clinical trials before the ASCO meeting. As a result, IMMU's share price dropped over 50% after the Company lost the opportunity to further validate IMMU-132 with the medical community and missed out on significant media exposure because of management's missteps.

- The Company's failure to deliver on its promise of signing a partnership or appropriate licensing agreement to move its only viable drug candidate, IMMU-132, through clinical development despite early clinical successes and the rarely-granted Breakthrough Therapy Designation by the FDA.

61. venBio also asserted that Immunomedics' capability to manufacture IMMU-132 in a commercial setting was a significant concern. According to the venBio, Immunomedics had experienced "[o]ngoing delays" in getting its manufacturing processes ready. venBio expressed that it was "skeptical of IMMU's communicated manufacturing strategy," and stated that "IMMU cannot manufacture

their product without world-class CMC (Chemistry, Manufacturing & Controls) operating flawlessly, which [Immunomedics] likely do[es] not have."

62. In response to these complaints, on February 10, 2017, the Company announced that it had entered into a $2 billion licensing agreement for IMMU-132 with Seattle Genetics. Under the terms of the licensing agreement, Seattle Genetics would be responsible for conducting a Phase 3 clinical trial for IMMU-132 in patients with mTNBC and submitting the BLA to the FDA for accelerated approval. Seattle Genetics would also be solely responsible for manufacturing and commercializing IMMU-132. In exchange, Seattle Genetics would pay Immunomedics a $250 million up-front payment, with the remaining $1.75 billion being contingent on the drug achieving certain clinical, development, regulatory and sales milestones. Immunomedics would retain the right to co-promote IMMU-132 in the United States by participating in 50% of the sales effort, subject to certain parameters set forth in the agreement.

63. While some investors cheered the announcement of the $2 billion licensing deal, which led to an increase in the Company's stock price, venBio immediately and strenuously objected to it. venBio thereafter filed a lawsuit against Immunomedics' former slate of directors, Seattle Genetics and Greenhill & Co., which served as adviser to Immunomedics, and Immunomedics as a nominal defendant. venBio condemned the deal as essentially giving away Immunomedics'

"crown jewel" at a price that was well below market. Essentially, venBio claimed the deal was a sale of Immunomedics to Seattle Genetics on the cheap and, at minimum, provided Seattle Genetics the right to acquire a large portion of Immunomedics common stock at a deep discount. venBio also objected to the deal on the basis that Immunomedics' then-Chief Scientific Officer David Goldenberg ("Goldenberg") (Immunomedics' founder), who was married to then-CEO and director Cynthia Sullivan ("Sullivan"), was eligible for various royalties and other payments as a result of the Seattle Genetics transaction, which were not subject to any maximum cap. venBio further alleged that the former directors stood to be awarded lucrative packages on the closing of the deal. Thus, according to venBio, the deal would have enriched Immunomedics directors and officers at the expense of venBio and other Immunomedics shareholders.

64. At the end of the proxy battle, venBio representatives (and defendants in this case) Aghazadeh, Canute, Hutt, and Islam ultimately gained seats on the Immunomedics Board of Directors. Each of these directors touted their extensive experience in the biotechnology industry and ability to successfully fast-track IMMU-132 to FDA approval and get it to market. For instance, according to venBio:

> Canute's specific expertise in the area of commercial biologics manufacturing (commonly referred to in the industry as Chemistry, Manufacturing, and Controls ("CMC")), as well as his extensive board experience with multiple pharmaceutical companies make him highly qualified to help run Immunomedics's business. In particular, Mr. Canute's experience and expertise in CMC will provide critical

assistance to the Company's development of IMMU-132, which cannot be manufactured successfully unless CMC operates flawlessly.

65. On May 5, 2017, following venBio's successful campaign to place its people on Immunomedics' Board of Directors, the Company announced that Seattle Genetics had agreed to terminate the licensing agreement and settle the related litigation with venBio. Additionally, the Company announced that Sullivan and Goldenberg were resigning from their positions at Immunomedics. Immunomedics, under the leadership of Aghazadeh, Canute, Hutt, and Islam, announced that the new Board of Directors had conducted a review of the strategy of the Company, including a review of the projected timeline for the BLA submission for IMMU-132. The Company also announced that the planned BLA filing date had slipped to "between late fourth quarter 2017 and first quarter 2018," and was "subject to FDA acceptance of the Company's chemistry, manufacturing and controls filing."

66. Around the time of the termination of the Seattle Genetics licensing agreement, Immunomedics hired defendant Rosenberg as an outside consultant to get the Morris Plains manufacturing plant ready for an FDA pre-approval inspection. In November 2017, Immunomedics announced that it hired defendant Pehl due to his "proven ability to successfully navigate the approval and commercialization of ground-breaking drugs in the oncology space – which we are confident IMMU-132 and other products in our pipeline will be." In February 2018, the Company

announced that Rosenberg would no longer be just a consultant, but had been hired as Immunomedics' CTO.

67. The scuttling of the Seattle Genetics deal left Defendants with the need to deliver on their commitment that Immunomedics, alone, could timely file the IMMU-132 BLA, and get the Morris Plains manufacturing facility ready for a robust FDA pre-approval inspection and commercial production. Indeed, after: (a) nearly 40 years of repeated failures to get a single drug approved by the FDA; (b) Aghazadeh, Canute, Hutt and Islam successfully removed Immunomedics management who were purportedly responsible for those failures; and (c) the repeated assurances to investors that the Company under new management could deliver IMMU-132 to the market, Defendants knew that any failure to do so would be harshly judged by investors and the market.

FDA Approval Process of Biologics

Biologics License Application – "BLA"

68. IMMU-132 is a biological pharmaceutical, or biologic. Biologics differ from conventional drugs in that a biologic is a large, complicated molecule that only comes from living systems or contains organic molecules, whereas non-biologic, small-molecule drugs largely come from chemicals. Often, biologics are injected while drugs are usually swallowed. Biologics are generally so large and complex that their exact structure is unknown. By contrast, conventional drugs have an

easily-identifiable chemical structure and can usually be analyzed to determine all their various components.

69. Prior to the marketing and sale of any biologic, the product must go through an extensive FDA approval process. The approval process includes completion of preclinical laboratory tests and animal studies, performance of clinical trials in humans, submission of a BLA, and FDA review and approval of the application.

70. While a new drug application ("NDA") is used for drugs, a BLA is required for biological products. The process is so similar, in fact, that the FDA Form 356h is used for both NDA and BLA submissions. Like an NDA submission, the BLA submission can be tens of thousands of pages long. The BLA similarly includes detailed information on the biologic, including the data and results from both the preclinical and clinical testing and trials, as well as information concerning the biologic's chemistry, manufacturing, controls and proposed labeling. The FDA evaluates the BLA to determine whether the biologic is safe and effective for its intended use. Additionally, and importantly, the FDA must make a determination that the manufacturing process and facilities meet applicable regulations and requirements to ensure the continued safety, purity and potency of the product. The regulations regarding BLAs for therapeutic biological products include 21 C.F.R. parts 600, 601, and 610.

71. The manufacturing process for a biological product is usually different from the manufacturing process of drugs. For biologics, "the product is the process," and biologics are often defined by their manufacturing processes. Whereas finished drugs can be replicated with 100 percent confidence in manufacturing sites across the globe, biologics are impossible to recreate with 100 percent accuracy. And while drug manufacturers can change the manufacturing process extensively and analyze the finished product to establish that it is the same as before the manufacturing change, biologic manufacturers must ensure product consistency, quality and purity by maintaining a substantially similar manufacturing process over time.

72. The living systems used to produce biologics can be sensitive to even very minor changes in the manufacturing process. Small changes in the manufacturing process, equipment or facilities can significantly affect the nature of the biological product itself and the way it functions in the body, sometimes requiring additional clinical studies to demonstrate the product's safety, identity, purity and potency. To ensure the manufacturing process remains the same over time, biologic manufacturers must tightly control the source and nature of starting materials, and consistently employ hundreds of process controls that assure predictable manufacturing outcomes. Because a tightly controlled manufacturing process for biologics is crucial, production is monitored by the FDA from the early stages to make sure the final product turns out as expected.

FDA Form 483

73. As part of the review process of a BLA, the FDA conducts what is known as a "pre-approval inspection" of the applicant's manufacturing facilities to ensure that the facility complies with applicable rules and regulations in manufacturing the biologic in question. These regulations are known as current Good Manufacturing Practice ("cGMP") regulations and compliance with cGMP includes an investigation of any deviations from cGMP regulations and the correction of those deviations if any are found. Failure to comply with cGMP may result in a variety of consequences, including subjecting a company to regulatory enforcement or a delay in the potential approval and commercialization of a biopharmaceutical product.

74. Immunomedics emphasized the importance of complying with cGMP in its annual reports on Form 10-K filed with the SEC. For example, the Company informed investors:

Manufacturing Regulatory Considerations

> In addition to regulating and auditing human clinical trials, the FDA regulates and inspects equipment, facilities and processes used in the manufacturing of such products prior to providing approval to market a product. If, after receiving approval from the FDA, a material change is made in manufacturing equipment, location, or process related to an approved product, additional regulatory review may be required. We must also adhere to cGMP and product-specific regulations enforced by the FDA through its facilities inspection program. The FDA also conducts regular, periodic visits to re-inspect equipment, facilities, and processes following the initial approval. If, as

> a result of these inspections, the FDA determines that our equipment, facilities or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may seek civil, criminal or administrative sanctions and/or remedies against us, including the suspension of our manufacturing operations.

75. According to the FDA, a notice on FDA Form 483 may be issued if an inspector finds conditions at a manufacturing facility to be in violation of the Federal Food, Drug and Cosmetic Act, cGMP or any other applicable regulations. A Form 483 logs observations seen during the course of the FDA inspection, and observations are made when an inspector determines that a drug has been adulterated or is being prepared, packed or held under conditions where the drug may be adulterated or become injurious to health due to conditions or practices that are not in compliance with regulations.

76. At the end of the inspection, a Form 483 is issued to the company's management if an observed violation has been made by FDA inspectors. In conjunction with the Form 483, each observation is read and discussed with management at the inspection "close-out" meeting so that the company understands the significance of each observation. Upon receipt of the Form 483 the company must adequately respond within 15 days with a corrective action plan that the company must then implement. The Form 483, the Establishment Inspection Report, any additional evidence/documentation and the company's responses thereto are collectively considered by the FDA in determining whether further action is needed.

Establishment Inspection Report – "EIR"

77. Subsequent to the completion of the FDA's inspection of a company's manufacturing facilities, the FDA inspectors prepare and issue a written Establishment Inspection Report ("EIR"). The EIR includes a detailed summary of the FDA inspection team's findings, details regarding a Form 483 (if issued), descriptions of failures or refusals by the company to remediate observed violations, whether the company is approved for distribution of the product at issue, summaries of interviews conducted by the inspectors, details on the company's training program and a description of the inspectors' tour of the facility. The EIR also includes any objectionable conditions noted by the inspectors, notates supporting evidence for the FDA's conclusions, and details management's responses to the observations during the inspection.

Complete Response Letter – "CRL"

78. The final step in the BLA review cycle is the issuance of either an approval letter or a CRL by the FDA. If a company receives a CRL, the FDA's review of the BLA is complete and the agency has determined that the product is not ready for approval. CRLs may also list additional data, clinical trials, preclinical studies, or remediation of manufacturing issues that may be required of the sponsor company prior to BLA approval. In addition, the FDA may request that the sponsor resubmit the BLA at a future date.

The Immunomedics Data Integrity Breach

79. On January 31, 2018, Immunomedics personnel internally reported a Data Integrity Breach that was discovered upon a review of analysis of bioburden data at the Morris Plains manufacturing facility. "[A]nd in the days immediately following" January 31, 2018, Pehl and the Board of Directors were notified of the Data Integrity Breach. Ex. A, App'x 1, at 2 of 29 (attached hereto). It bears emphasis, moreover, that the Data Integrity Breach was so serious that Immunomedics informed the FDA of the Data Integrity Breach "immediately upon [its] discovery" on January 31, 2018. *Id.* at 4 of 29. Defendants immediately identified the Data Integrity Breach as "a matter deserving [their] utmost attention," and brought in outside counsel to investigate the Data Integrity Breach under the cloak of attorney-client privilege. *Id.* at 2 of 29.

80. Immunomedics had originally informed investors that it would be filing the IMMU-132 BLA with the FDA in March 2018. Due to Defendants' discovery of the Data Integrity Breach on January 31, 2018, Defendants knew they needed additional time to begin the process of resolving it. Accordingly, on February 8, 2018 after the market closed, Immunomedics told the investing public that it was pushing its BLA filing date out by two months. In announcing the delay, however, Defendants deliberately concealed from investors any and all information regarding the Data Integrity Breach.

81. To avoid investor outrage with another delay, on May 21, 2018, Immunomedics submitted the BLA to the FDA for IMMU-132. On July 18, 2018, the application was accepted and scheduled to be reviewed by the FDA within six months. Pehl claimed the submission of the BLA for IMMU-132 was a "significant milestone" for the Company and told investors "[w]e will continue to work closely with the [FDA] as we strive to bring this potential new treatment to mTNBC patients expeditiously." But, again, Pehl said nothing about the Data Integrity Breach.

82. Between August 6 and August 14, 2018, the pre-approval inspection of Immunomedics' manufacturing facilities was conducted in Morris Plains, New Jersey. *See* Exs. B, C (attached hereto). The FDA issued a Form 483 to Pehl and Immunomedics on August 14, 2018, immediately following the completion of the inspection and after consulting with the Company about the agency's findings. Ex. B. The FDA inspectors logged 13 observations on the Form 483, the first two of which related to the Data Integrity Breach. *Id*. The FDA inspectors determined that the Data Integrity Breach should have triggered a deviation that should have been investigated by the Company's quality control unit, but no deviation was generated. *Id.* at 1. The Form 483 identified that the Data Integrity Breach included "manipulation of bioburden samples, misrepresentation of the [REDACTED] integrity test procedure in the batch record and backdating of batch records, including dates of analytical results." Ex. B at 1. Moreover, the Form 483 stated

that the FDA could make no assessment whether the Data Integrity Breach had been remediated because documentation necessary to make that assessment was deliberately withheld by Defendants pursuant to attorney-client privilege. *Id*.

83. On September 4, 2018, Immunomedics issued a 29 page response to the Form 483, but did not make it publicly available. *See* Ex. A. Immunomedics' response conceded that the Data Integrity Breach had first been raised internally on January 31, 2018, and that defendants Pehl, Aghazadeh, Canute, Hutt and Islam had been notified of the Data Integrity Breach immediately following its discovery. *Id.*, App'x 1 at 2 of 29. Immunomedics also confirmed that its internal investigation determined that "employee misconduct [was] identified and verified" and resulted in the "separation of three managers from the Company." *Id.* As a result of the Form 483 observations concerning the Data Integrity Breach, Immunomedics informed the FDA that it had implemented several changes, including the issuance of an Ethical Conduct and Data Integrity corporation policy, initiation of a Data Governance Program and training on data integrity and good documentation practices. *Id*. at 3 of 29.

84. Between September 26 and 27, 2018, the FDA inspectors responsible for the agency's pre-approval inspection of the Morris Plains manufacturing facility, signed the EIR, which contained a detailed narrative of the events that occurred during the August 6-14, 2018 pre-approval inspection. *See* Ex. C. At bottom, the

EIR contained the factual underpinnings of the FDA inspectors' observations listed in the August 14, 2018 Form 483 issued to Pehl. The EIR, comprised of a 59-page report plus numerous attachments and exhibits, confirmed that the Data Integrity Breach had been discovered during the review of the bioburden data in January 2018. The EIR also confirmed that the status of the Data Integrity Breach could not be ascertained because of Immunomedics' repeated invocation of the attorney-client privilege to withhold documentary proof to back up Defendants' verbal claims regarding the scope and remediation of the Data Integrity Breach. *Id*., App'x at 41-42.

85. With respect to the manipulation of bioburden samples, the EIR noted that "in-process samples were [REDACTED] by the manufacturing operators prior to be submitted to the QC lab for analysis" and the manipulation "was conducted to prevent potential bioburden non-conformances of the samples." *Id*. at 40. The inspectors also determined that an integrity test in the batch record was compromised and "would not have detected any failure in the integrity." *Id*. The EIR also stated that "operators recorded the operations later using the date when the operation was supposed to be recorded." The inspectors found that the backdating "included information regarding manufacturing operations and input of analytical data." *Id*.

86. The EIR went on to describe the FDA inspectors' interactions with Immunomedics management and their repeated refusal to provide any evidence

concerning their verbal claims concerning the scope and purported resolution of the Data Integrity Breach. Specifically, the EIR detailed an inspector's communications with Rosenberg, who was identified as the "most responsible person at the facility at the start of the inspection." *Id.* at 1. An FDA inspector noted in the EIR that he had asked Rosenberg for additional information concerning the Data Integrity Breach, but was only given limited information in response. *Id.* at 40. Rosenberg's initial response was that the Data Integrity Breach had been discovered through an analysis of historical bioburden data in January 2018, and that only two procedures were impacted – manipulation of the bioburden samples and misrepresentation of the integrity test procedures. *Id.* However, the inspector observed that Rosenberg failed to disclose the issue related to the integrity test procedures discovered by Immunomedics in January 2018 until the inspector directly asked about it. *Id*.

87. As described in the EIR, on August 9, 2018, the FDA inspector asked Rosenberg again about the Data Integrity Breach, and inquired if it only impacted the two procedures Rosenberg had previously disclosed to him. *Id*. Rosenberg finally conceded that a third procedure had been impacted, which related to the backdating of records. *Id*. Subsequently, the FDA investigator requested information concerning Immunomedics' investigation/deviation of the Data Integrity Breach, and management was forced to admit that no deviation had been initiated. Rosenberg claimed that remediation steps had been taken but refused to

honor the FDA's repeated requests for documentation supporting this verbal claim, asserting attorney-client privilege over the documents (which included interview transcripts from the investigation of the Data Integrity Breach performed by outside counsel). *Id.* at 40-41.

88. The EIR also revealed the FDA inspector's determination that the scope of the Data Integrity Breach was much broader than what had initially been disclosed to the FDA in Immunomedics' early 2018 letter to the agency, which had only identified the manipulation of the bioburden samples. *Id.* at 41. The inspector noted that while Immunomedics had provided an update to the FDA (prior to the August 2018 inspection), the Company had again failed to disclose that any additional procedures had been impacted by the Data Integrity Breach. *Id.*

89. On August 9, 2018, Rosenberg gave the FDA inspector a document that he represented was information given to the firm's outside counsel investigating the Data Integrity Breach. *Id*. at 42. But the FDA inspector noted that the document was dated August 7, 2018 and was nothing more than a summary of what Rosenberg had verbally claimed during the inspection. Regardless, the inspector requested to keep a copy of this document for the FDA's records, but Rosenberg refused. *Id.* Accordingly, the EIR logged the FDA inspectors' determination that "no verbal information could be verified during the inspection because the firm refused to provide" documentary proof. *Id.* at 41.

90. During the inspection, the FDA inspectors attempted to assess the impact of the Data Integrity Breach through a review of the Company's historical bioburden data. Although Rosenberg insisted throughout the inspection that the Data Integrity Breach had stopped before the process performance qualification ("PPQ") campaign, which was initiated August 1, 2017, the FDA inspector determined after testing the bioburden samples that the Data Integrity Breach "was ongoing during the PPQ campaign and possibly during the commercial campaign." *Id.* at 44 of 66. The FDA inspector found no evidence to support Rosenberg's verbal claim. *Id*.

91. In response to the FDA inspectors' findings, Immunomedics' management "indicated at the [August 14, 2018] inspection close-out that they understood the seriousness of the observation[s] and they would respond to the FDA." *Id*.

92. The EIR was provided to Immunomedics and the Individual Defendants on February 6, 2019. Within three weeks of its receipt, Pehl was forced to resign.

DEFENDANTS' MISLEADING STATEMENTS AND MATERIAL OMISSIONS

93. After the market closed on February 8, 2018, Immunomedics issued a press release and thereafter filed a Form 8-K, signed by Garone and attaching the press release, with the SEC. The press release, reviewed and approved for

publication by Pehl and Garone was entitled "Immunomedics Announces Second Quarter Fiscal 2018 Results and Provides Corporate Update." In the press release, Pehl stated:

> ***I am pleased with the overall progress across clinical and manufacturing work streams, including successful validation runs. Our focus continues to be on compiling a BLA package that efficiently brings [IMMU-132] to market, and one that anticipates and addresses potential FDA requests going forward. As such, we now expect to file the BLA by the end of May 2018***.

The press release further announced that Rosenberg had joined the Company as CTO and would focus on preparing IMMU-132 for commercial launch, including developing a robust CMC package for the BLA submission.

94. Immediately after the Company issued its February 8, 2018 press release, Immunomedics held a conference call with analysts and investors to discuss, among other things, the Company's second fiscal quarter of 2018 ("2Q18") financial results, the status of the IMMU-132 BLA and pre-approval inspection efforts at the Morris Plains manufacturing facility. Pehl and Rosenberg participated in the conference call. During Pehl's opening remarks, he stated:

> We continue to work diligently and have made significant progress towards the filing of our BLA. Since joining the company, I have asked for a thorough review of all submission and site inspection related work streams to ensure highest quality of our filing documents and manufacturing and inspection preparedness efforts. ***I'm very pleased with the overall status and quality and can confirm that all critical work streams, including, for example, the previously discussed manufacturing validation runs, are yielding positive results. We are tracking slightly behind our previously***

> ***communicated time schedule, as we seek to compile the most complete package possible that anticipates future FDA requests***. We therefore now anticipate filing the BLA by the end of May 2018.

95. Later in the February 8, 2018 conference call, Pehl and Rosenberg engaged in the following exchange with Philip M. Nadeau ("Nadeau"), an equity analyst for Cowen & Co.:

> [NADEAU:] I guess, first question is on the BLA timelines. As you suggested, they're a couple difference versus prior guidance. Could you talk a little bit more about what gave rise to that? Was it simply some of the work streams that you are working on are a little bit – going a little slower than maybe you initially anticipated? Or is it more that in looking through the filing, Michael, you decided that there is some analyses that should be in there to anticipate potential questions from the FDA?
>
> [PEHL:] Yes, this is Michael. Thanks, Phil, for the question. So let me start by saying that I'm really very pleased with the overall status and the quality of the CMC and clinical submission package. ***And that I can really confirm that all the critical submission-related work streams, including, for example, the previously discussed manufacturing validation runs, are providing positive results***. There [are] 2 principal reasons for why we are now guiding to a submission date at the end of May, which represents a change of about 2 months. And Morris Rosenberg, who is with me in the room, will provide you with a bit more detail in a minute. The first is that we had a very important pre-BLA CMC meeting with the agency in January, during which they requested that we do 3 additional assays.
>
> ***We adjusted our original schedule to allow sufficient time to validate these assays and incorporate the data into our BLA submission package. So that was reason number one. Reason number two is that we had very aggressive initial time lines associated with the validation of the bioanalytical assays and testing for literally thousands of animal and human PK samples***. And it has just taken us longer than originally anticipated to complete the assay validations, run the samples and incorporate the data into the BLA submission. So

> we're making really rapid progress and good progress on both of these fronts, and we are very confident that we will meet our new date of end of May. And I just want to hand over to Morris for providing a little bit of detail and flavor.
>
> [ROSENBERG:] Sure. Thank you, Michael. We've made tremendous progress over the last 6 months in process validation, assay validation and so forth. And Michael mentioned that we had the pre-BLA meeting focused on CMC with the FDA. We have an excellent working relationship with the FDA. At that most recent CMC pre-BLA meeting that we had with the agency in January, they requested that we add 3 assays to our package. One assay is a routine assay that measures endotoxin and other pyrogens in an animal model, and the FDA asked us to do this assay on 3 demonstration batches. And we have already performed a very similar assay in vitro that measures the same parameters, measures endotoxin. ***So this is very much sort of a check-the-box exercise. Nonetheless, we have to go through validation and incorporate the data into the BLA***.

96. Later in the February 8, 2018 conference call, Rosenberg engaged in the following exchange with James W. Birchenough ("Birchenough"), an equity analyst for Wells Fargo:

> [BIRCHENOUGH:] Congrats, Michael and Morris, on the new roles and the progress. So I wanted to follow up on Phil's questions, just around the manufacturing. You talked about making great progress in these validation assays, but could you comment on the performance? How much visibility you have from FDA in terms of release criteria? And how these assays are performing relative to the release criteria? The impetus of the question is just to understand whether there's any potential risk in these validation assays.
>
> [ROSENBERG:] Yes, thanks for the question. ***So the FDA does have a lot of visibility. So we've had a couple of face-to-face meetings with them and written communications with them. We – they have seen our proposed release assays. They have seen our whole manufacturing process, the process flow diagrams and so forth. They have seen our proposed release assays, and it was in that discussion,***

> ***actually, that they made the suggestion for the 3 additional assays. We discussed it with them and agreed with them that we should put those in place and are doing that***. And these are, as I was saying before, fairly standard assays. And we have already characterized our process by either very similar assays or exactly these assays. So it's really just an exercise in going through the tailoring to our product and then the validation and then importing the data into the appropriate sections of the BLA.

97. On February 8, 2018, after Defendants conducted the 2Q18 earnings call, Immunomedics filed its 2Q18 Form 10-Q with the SEC. Defendants Pehl and Garone singed the 2Q18 Form 10-Q. The 2Q18 Form 10-Q contained the following risk disclosure:

> We face a number of risks relating to the maintenance of our information systems and our used of information relating to clinical trials.
>
> In managing our operations, we rely on computer systems and electronic communications, including systems relating to record keeping, financial information, sourcing, and back-up and the internet ("Information Systems"). Our Information Systems include the electronic storage of financial, operational, research, patient and other data. ***Our Information Systems may be subject to interruption or damage from a variety of causes, including power outages, computer and communications failures, system capacity constraints, catastrophic events (such as fires, tornadoes and other natural disasters), cyber risks, computer viruses and security breaches***. If our Information Systems cease to function properly, are damaged or are subject to unauthorized access, we may suffer interruptions in our operations, be required to make significant investments to fix or replace systems and/or be subject to fines, penalties, lawsuits, or government action. The realization of any of these risks could have a material adverse effect on our business, financial condition and results of operations. Our clinical trials information and patient data (which may include personally identifiable information) is part of our Information

Systems and is therefore subject to all of the risks set forth above, notwithstanding our efforts to code and protect such information.

98. On February 22, 2018, the Company participated in the RBC Capital Markets Healthcare Conference. During the conference, Pehl engaged in the following exchange with Kennan McKay ("McKay"), an RBC Capital Markets equity analyst:

> [MACKAY:] And just putting the prior checkpoint treatment into context, I think that exemplifies how desperate these patients really are. Because this isn't exactly an immunologically hot tumor. This is perhaps one of the colder tumor types out there where checkpoints really don't see activity.
>
> So putting this into context, what are sort of the next steps and timelines associated with the regulatory submission? What else does need to get done?
>
> [PEHL:] So we communicate[d] in our earnings call that the timeline or the time point of our submission is end of May. ***We had previously communicated a timeline that was a couple of [months] earlier, but there is some additional work ongoing in terms of assays that the FDA has been asking us to do***. And PK work that just needs to be finished and finalized in the right quality and that has shifted the timeline a little bit.
>
> ***The other work stream that is ongoing and where we have really made great progress is process validation***. So doing validation runs of the antibody, of the linker, of the conjugation and of the fill/finish. Most of that work is done, so the antibody work is done.
>
> The linker work is almost done and we are now doing the last work with our partner BSP in Italy, who does the conjugation fill/finish. So we are really going to come in very nicely against that timeline.
>
> The third major thing for us is preparing for a preapproval inspection. That's what the FDA usually does. That's totally not unusual for our Company. Every company with a biologic gets that.

> ***We hired someone as our head of quality who has eight years of experience as an FDA inspector. She turns basically every stone between New Jersey and New York, I can tell you. And she also brought in a lot of consultants with an FDA background, so we feel that we are extremely well prepared***.
>
> Submission is front and center for us without any doubt. But I think we are doing extremely well against the timelines and the work that needs to be done.

99. On May 9, 2018, Immunomedics held a conference call with analysts and investors to discuss, among other things, the Company's third fiscal quarter of 2018 ("3Q18") financial results and provide a corporate update. Pehl participated in the conference call. During the call, Immunomedics and Pehl published to analysts and investors a PowerPoint presentation entitled "Corporate Overview, May 2018." The presentation outlined ongoing activities related to the Morris Plains manufacturing facility, as well as IMMU-132 supply in anticipation of commercial launch of the drug. Defendants' PowerPoint presentation informed investors that completing chemistry, manufacturing and controls preparations in advance of the FDA pre-approval inspection of the Morris Plains facility was a "***Key 2018 Business Objective[]***," "***[p]re-approval inspection activities continue***" and that manufacturing "***[p]rocess [v]alidation***" was ongoing in anticipation of the FDA's pre-approval inspection.

100. On May 9, 2018, Immunomedics filed its 3Q18 Form 10-Q with the SEC. Defendants Pehl and Garone signed the 3Q18 Form 10-Q. The 3Q18 Form

10-Q contained the identical misleading risk disclosure (contained in the 2Q18 Form 10-Q) concerning the Company's information systems. *See* ¶97, *supra.*

101. On June 4, 2018, Immunomedics issued a press release containing its presentation the prior day at the ASCO annual meeting in Chicago, Illinois. During the Company's presentation, and with regard to additional manufacturing testing the FDA had requested Immunomedics complete before submitting the BLA, Pehl stated: "***I think we did really, really with the additional time that we gave ourselves due to feedback of FDA who wanted to have some additional assay information and was also very useful for us in order to make sure [the BLA] comes in the highest possible quality***."

102. On June 11, 2018, Defendants filed a Form S-3ASR Registration Statement (the "Registration Statement") with the SEC for a follow-on offering of securities, including common stock. Defendants Pehl, Garone, Aghazakeh, Canute, Hutt and Islam signed the Registration Statement pursuant to the Securities Act of 1933. The Registration Statement incorporated by reference the risk disclosure language from the Company's 2017 Form 10-K regarding the Company's information system. That incorporated language is identical to the risk disclosure language contained in the Company's 2Q18 Form 10-Q. *See* ¶97, *supra*. The Registration Statement, however, failed to disclose the Data Integrity Breach discovered by the Company in January 2018.

103. On June 14, 2018, Defendants filed a Form 424B5 Prospectus ("Prospectus") for the offering of at least 11.5 million shares of common stock at a price of $24.00 per share. The Prospectus contained identical risk disclosure language regarding the Company's information systems as identified in the Company's 2Q18 Form 10-Q. *See* ¶97, *supra*. Like the Registration Statement, the Prospectus failed to disclose the Data Integrity Breach.

104. On June 15, 2018, the Company issued a press release entitled "Immunomedics Announces Closing of Public Offering of Common Stock." The Company announced that total net proceeds from the 11.5 million share offering were $260 million (after deducting underwriting discounts and commissions, etc.). Subsequently, the Company disclosed in its 2018 Annual Report on Form 10-K that it had issued an additional 1.725 million shares pursuant to the underwriters' full exercise of the over-allotment option, bringing the total net proceeds for the June 2018 offering to approximately $300 million. The Company announced that it intended to use the proceeds from the June offering for, among other things, manufacturing process improvements.

105. Defendants' statements, made between February 8, 2018 and June 14, 2018, were materially misleading when made and omitted to disclose material facts necessary to not make the statements made misleading, because Defendants failed to disclose that as discovered on January 31, 2018, Immunomedics suffered a Data

Integrity Breach at its Morris Plains manufacturing site for IMMU-132. The scope of the Data Integrity Breach included personnel working for Immunomedics at the Morris Plains facility who had deliberately manipulated bioburden samples of IMMU-132, deliberately backdated batch records, including the dates of analytical results conducted by Immunomedics, and deliberately falsified information in the batch records related to the manufacturing process of IMMU-132. As a result of its severity, the FDA was alerted about the Data Integrity Breach immediately upon its discovery in January 2018.

106. On August 23, 2018, Immunomedics filed its 2018 Form 10-K with the SEC. Defendants Pehl, Garone, Aghazakeh, Canute, Hutt and Islam signed the 2018 Form 10-K. The 2018 Form 10-K contained the identical misleading risk disclosure contained in the Company's prior regulatory filings concerning the Company's information systems. *See* ¶97, *supra*. The 2018 Form 10-K also contained risk disclosure language concerning the Company's ***potential*** receipt of a Form 483 from the FDA (even though Immunomedics had actually received the Form 483 nine-days earlier on August 14, 2018):

> ***If we, or any of our collaboration partners, or our or their contract manufacturers, cannot successfully and efficiently manufacture the compounds that make up our products and product candidates, our ability, and the ability of our collaboration partners, to sell products and conduct clinical trials will be impaired***.
>
> Our ability to conduct our preclinical and clinical research and development programs depends, in large part, upon our ability to

> manufacture our proprietary compounds in accordance with the FDA and other regulatory requirements. We have limited historical experience in manufacturing these compounds in significant quantities, and we may not be able to do so in the quantities required to commercialize these products. Any interruption in manufacturing at this site, whether by natural acts or otherwise, could significantly and adversely affect our operations, and delay our research and development programs.
>
> We and our collaboration partners also depend on third parties to provide certain raw materials, and contract manufacturing and processing services. All manufacturers of biopharmaceutical products must comply with current [Good Manufacturing Practice regulations or cGMPs], required by the FDA and other regulatory agencies. Such regulations address, among other matters, controls in manufacturing processes, quality control and quality assurance requirements and the maintenance of proper records and documentation. The FDA and other regulatory agencies routinely inspect manufacturing facilities, including in connection with the review of a BLA. ***The FDA generally will issue a notice on Form 483 if it finds issues with respect to its inspections, to which the facility must adequately respond in order to avoid escalated regulatory concerns. If our manufacturing facility or those facilities of our collaboration partners and our respective contract manufacturers or processors do not comply with applicable cGMPs and other regulatory requirements, in addition to regulatory enforcement, we may be subject to product liability claims, we may be unable to meet clinical demand for our products, and we could suffer delays in the progress of clinical trials for products under development and of potential approval and commercialization***.

107. On August 24, 2018, the day after Garone signed the Company's 2018 Form 10-K and 10 days after the Company received the FDA's Form 483, Immunomedics announced that Garone had resigned from his position as CFO effective August 23, 2018. The Company further announced that Malik would serve as Immunomedics' interim CFO.

108. On November 7, 2018, Immunomedics held a conference call with analysts and investors to discuss, among other things, the Company's first fiscal quarter of 2019 ("1Q19") financial results and provide a corporate update. Pehl participated in the call. During the call, Pehl stated:

> [The] Company has made significant progress in the first fiscal quarter as we continue to focus on our regulatory, clinical, manufacturing and launch-preparatory efforts. ***Based on recent mid-cycle discussion with the FDA, the company will continue to work closely and collaboratively with the agency to address outstanding review issues*** . . . .

109. Pehl's comment during the November 7, 2018 conference call led multiple analysts to ask about "issues" with the FDA, to which Pehl responded that "the nature of our ongoing discussions with the agency are very confidential and sensitive" and "we are working very closely and collaboratively with the agency."

110. Immunomedics' stock price promptly declined following the vague warning about "issues" with the FDA. In response, Defendants made misleading statements through friendly sell-side analysts to falsely assure investors that there were no material issues with the FDA. At approximately 2:08 p.m. on November 8, 2018, Wells Fargo analysts reported of their discussions with Immunomedics management: "We spoke with management earlier today to clarify and gain context and understand that outstanding questions are in line with that expected in the normal course of [the] BLA review." Approximately one hour later, Morgan Stanley analysts reported of their discussions with Immunomedics management: "We spoke

with mgt. who clarified that what they were trying to communicate was that the review is 'on-going' and proceeding as a normal review would, with back and forth with the FDA."

111. On November 7, 2018, after the earnings call, Immunomedics filed its 1Q19 Form 10-Q with the SEC. Defendants Pehl and Malik signed the 1Q19 Form 10-Q. The Form 10-Q contained the identical misleading risk disclosure (contained in the 2018 Form 10-K) concerning the Company's information systems. *See* ¶97, *supra*. The 1Q19 Form 10-Q also contained the identical misleading risk disclosure (contained in the 2018 Form 10-K) concerning FDA regulation of the manufacturing process and the implications if a Form 483 was received from the FDA. *See* ¶106, *supra*.

112. The 1Q19 Form 10-Q also added a new risk factor relating to, among other things, Immunomedics employees who "may engage" in fraudulent conduct or other illegal activity that violates FDA laws, manufacturing standards and the federal securities laws. Specifically, the new risk factor Defendants caused Immunomedics to list in the 1Q19 Form 10-Q stated:

> ***Our employees and our independent contractors, principal investigators, consultants or commercial collaborators, as well as their respective sub-contractors, if any, may engage in misconduct or fail to comply with certain regulatory standards and requirements, which could expose us to liability and adversely affect our reputation.***
>
> Our employees and our independent contractors, principal investigators, consultants or commercial collaborators, as well as their

> respective sub-contractors, if any, may engage in fraudulent conduct or other illegal activity, ***which may include intentional, reckless or negligent conduct that violates, among others, (a) FDA laws and regulations, or those of comparable regulatory authorities in other countries, including those laws that require the reporting of true, complete and accurate information to the FDA, (b) manufacturing standards***, (c) healthcare fraud and abuse laws or (d) laws that require the true, complete and accurate reporting of financial information or data. For example, such persons may improperly use or misrepresent information obtained in the course of our clinical trials, create fraudulent data in our preclinical studies or clinical trials or misappropriate our drug products, which could result in regulatory sanctions being imposed on us and cause serious harm to our reputation. It is not always possible for us to identify or deter misconduct by our employees and third parties, and any precautions we may take to detect or prevent such misconduct may not be effective. ***Any misconduct or failure by our employees and our independent contractors, principal investigators, consultants or commercial collaborators, as well as their respective sub-contractors, if any, to comply with the applicable laws or regulations may expose us to governmental investigations, other regulatory action or lawsuits. If any action is instituted against us as a result of the alleged misconduct of our employees or other third parties, regardless of the final outcome, our reputation may be adversely affected and our business may suffer as a result. If we are unsuccessful in defending against any such action, we may also be liable to significant fines or other sanctions, which could have a material and adverse effect on us***.

Defendants, however, failed to inform investors that the Company had already concluded that Immunomedics employees engaged in the precise conduct set forth in the risk disclosure. Specifically, as part of the Data Integrity Breach, Immunomedics employees engaged in the deliberate and fraudulent conduct of falsifying manufacturing processes and documentation relating to the operational status of the Morris Plains manufacturing facility. Defendants, moreover, failed to

inform investors that they had made a deliberate decision to withhold disclosure of the details of that fraudulent conduct, as well as the Company's August 14, 2018 receipt of the Form 483 and the content of the Form 483 that explicitly referenced that deceptive conduct.

113. On November 13, 2018, the Company participated in the Credit Suisse Healthcare Conference. During the conference, Malik stated:

> ***Where we are today is we're in a good state to supply the market for the next few years based on the current [Morris Plains manufacturing] infrastructure that we have***. But we've timed bringing up the second and third sourcing of the supply chain in order to have them up and running, so that at no point do we have a risk in the supply chain or supplying the market. And we've also done significant amount of analysis on upside scenarios to understand if they are – if there's prescriptions that are happening in earlier line or off-label prescriptions or other indications come to market or as we expand geographically over the next could of year [sic], what are the implications on supply. And again based on that modeling, we're continuing to scale the supply chain, accordingly.

114. As described in further detail below, on December 20, 2018, Dr. Favus issued an equity analyst report disclosing in further detail the contents of the August 14, 2018 Form 483 and the conclusions made by FDA inspectors during the August 6 through August 14, 2018 pre-approval inspection of the Morris Plains manufacturing facility. This revelation, which disclosed only a part of Defendants' fraudulent conduct, also raised fears that the FDA would not approve the IMMU-132 BLA.

115. As a consequence, Defendants made additional misleading statements through friendly sell-side analysts to assure investors that their concerns were overblown. For example, around 10:00 a.m. on December 20, 2018, Guggenheim analysts reported of their discussions with Immunomedics management:

> According to IMMU management, a competitor research report published this a.m. highlighted IMMU's receipt of an FDA Form-483, citing manufacturing issues regarding sacituzumab, which is currently under FDA review (1/18/2019 PDUFA). ***We spoke with management who pointed out to us that this Form-483 was already received 4 months ago, this August, and the company believes it has addressed manufacturing issues cited in the form***.

116. Approximately one hour later, Morgan Stanley analysts reported on their discussions that morning with Immunomedics management:

> We spoke with mgt. who indicated that these issues were discovered as part of their ramp to GMP quality in late 2017/early 2018 and that mgt. began remediation of the issues well prior to the 483. ***Mgt. believes they have communicated with the FDA about the issues prior to the 483 and have worked to remediate all the key issues. Mgt. further indicated that if these issues, including the 483, were material they would have issued a release highlighting the issues***. Finally, mgt. indicated that in general, the issues can be resolved both as pre or post approval commitments and that a follow-up inspection, while possible, is not required for approval. Given that investors have been worried about manufacturing issues potentially impacting the approval of IMMU-132, we understand the concern in the market. However, given what we see as resolvable issues and the fact that mgt. began remediation with FDA prior to the documentation in the 483, while these issue may pose approval risk, we still believe there is a higher probability of approval than not on the PDUFA.

117. Then, at approximately 11:30 a.m. on December 20, 2018, Wells Fargo analysts reported of their discussions with Immunomedics management:

> ***We have spoken with management this morning regarding observations and understand that they occurred as part of a pre-approval inspection in early August following BLA acceptance and granting of priority review status in July and that the observations are "old news" and a remediation has long been put in place***.
>
> We understand from IMMU management that observations from the FDA pre-approval inspection were "surfaced" by new management ***18-19 months ago*** and have been a focus of remediation efforts even in advance of the FDA inspection. ***While IMMU, appropriately, will not characterize FDA response to remediation efforts so close to a PDUFA date the company suggested that if there are major risks to the filing it would have to disclose more specifics***.

118. Shortly before 1:00 p.m. on December 20, Piper Jaffray also issued a report based on statements from Immunomedics, stating:

> We spoke with IMMU which emphasized that some observations were flagged and discussed with the FDA well ahead of the inspection and that it continues to interact with the FDA on almost a daily basis. At this stage, it is "dotting the I's and crossing the T's" and IMMU feels that it is in a very good place.

119. Finally, after the market close on December 20, a Jefferies analyst issued a report based on statements from Immunomedics, stating:

> IMMU traded down 20+% today on negative commentary related to an FDA inspection of the manufacturing site for the hRS7 antibody component of '132.
>
> * * *
>
> ***As above, the company confirmed that it received the inspection reports in August of this year, and feel that it has addressed all of the issues raised during the inspection. While mgmt did not disclose specific content, they were outwardly confident that everything was adequately addressed, and further that they are confident in a positive decision by the FDA on or before the Jan PDUFA date***.

120. On January 10, 2019, the Company participated in the J.P. Morgan Global Healthcare Conference. During the Company's presentation, and in response to an unidentified securities analyst's question concerning the "issues" identified by the FDA in the August 14, 2018 Form 483, Pehl stated: "This is a regulatory question, and I said, in the beginning that I would not comment on a regulatory question." Despite Pehl's insistence that he would not comment on the Form 483, he nonetheless assured analysts and investors: "***We've got the [Form] 483s in August. We did take care of [the issues] very early***."

121. Defendants' statements, made after August 14, 2018 and through January 17, 2019, were materially misleading when made and omitted to disclose material facts necessary to not make the statements made misleading, because Defendants failed to disclose:

(a) As discovered on January 31, 2018, Immunomedics suffered a Data Integrity Breach at its Morris Plains manufacturing site for IMMU-132. The scope of the Data Integrity Breach included personnel working for Immunomedics at the Morris Plains facility who had deliberately manipulated bioburden samples of IMMU-132, deliberately backdated batch records, including the dates of analytical results conducted by Immunomedics, and deliberately falsified information in the batch records related to the manufacturing process of IMMU-132. As a result of its

severity, the FDA was alerted about the Data Integrity Breach immediately upon its discovery in January 2018;

(b) Throughout the Class Period and particularly during the August 6-14, 2018 FDA pre-approval inspection of the Morris Plains manufacturing facility, Immunomedics failed to provide the FDA with written evidence to back up its verbal claims regarding the scope of the Data Integrity Breach, in addition to written information that would confirm Immunomedics' claims that it had purportedly resolved the Data Integrity Breach. Between August 6 and 14, 2018, during the FDA's pre-approval inspection of the Morris Plains facility, FDA inspectors repeatedly asked the Company to produce the results of the outside law firm's investigation into the scope and purported resolution of the Data Integrity Breach, but Defendants refused to provide it to the FDA on the basis that it was protected by the attorney-client privilege. Accordingly, by the close of the August 14, 2018 pre-approval inspection, the FDA was unable to make an assessment of the scope of the Data Integrity Breach or whether it had ever been resolved;

(c) On August 14, 2018, the FDA issued a Form 483 to Pehl for the Morris Plains pre-approval inspection. The Form 483 reflected the top-line findings of the FDA inspectors who conducted the pre-approval inspection of the Morris Plains facility. The Form 483 stated that the Data Integrity Breach included the manipulation of bioburden samples, misrepresentation of drug manufacturing

integrity testing procedures and backdating of batch records, including the dates of the analytical results; and

(d) With regard to Defendants' Class Period statements and omissions made after September 4, 2018, those statements were materially misleading when made for the additional reason that Defendants knew that their September 4, 2018 final written response to the Form 483 again failed to provide the FDA with the documentary evidence the agency had repeatedly asked for during the August 8 through 14, 2018 pre-approval inspection, and expressly noted in the Form 483. The FDA had requested this information for the purpose of verifying Immunomedics' verbal assertions concerning the purported scope and remediation of the Data Integrity Breach. By no later than September 4, 2018, therefore, Defendants knew that the FDA would remain unable to make an assessment of Immunomedics' verbal claims concerning the scope and resolution of the Data Integrity Breach. For the same reason, Defendants knew that the FDA would most likely reject the BLA.

DISCLOSURES OF THE TRUTH

122. Before the market opening on December 20, 2018, Favus issued an analyst report that disclosed further details of the Form 483, Data Integrity Breach and cGMP violations identified by the FDA during its inspection of the Morris Plains facility. Specifically, Favus revealed that the FDA had issued a Form 483 to Pehl

and Immunomedics on August 14, 2018, as a result of the agency's August 6 through August 14, 2018 pre-approval inspection. It was also disclosed that the Form 483 noted "'[i]nterviews [of] Immunomedics personnel involved in the [Data Integrity Breach] were conducted under attorney/client privilege and no additional documentation is available . . . [Thus] no assessment could be made'" of the extent of the Data Integrity Breach.

123. As a result of this news, Immunomedics' share price on the Nasdaq fell to a low of $12.96 during the trading day on December 20, 2018, or 27% from the prior day's closing of $17.46. To respond to the Favus Report, and as alleged herein, Pehl and Immunomedics contacted friendly sell-side analysts for purposes of defending the Company's stock price. *See* ¶¶115-120, *supra*. Within hours, several sell-side analysts published additional false claims made by Immunomedics management such as: The information in the Favus Report was "old news"; "many of the [FDA's] observations were flagged by an internal [Immunomedics] audit ahead of the inspection and discussed with the FDA beforehand. These issues were resolved rapidly after the inspection . . ."; and "remediation has long been put in place." As a result of these misleading statements, Immunomedics' stock price partially recovered during the trading day, and closed at $14.17 per share on December 20, 2018, down $3.47 from the December 19, 2018 close.

124. After the market closed on January 17, 2019, Immunomedics announced it had received a CRL from the FDA, which rejected the approval of IMMU-132. Defendants acknowledged that "[t]he issues [in the CRL] were exclusively focused on Chemistry, Manufacturing and Control matters . . . ." Immunomedics further stated that it intended to continue discussions with the FDA regarding the contents of the CRL.

125. The next morning, on January 18, 2019, and before the market opened, Immunomedics conducted a special conference call to discuss the CRL. During Pehl's opening remarks, he confirmed that the issues identified by the FDA in the CRL "related to the approvability [of IMMU-132]" and "were exclusively focused" on CMC matters. During the conference call, Pehl made the following statements during a discussion with Guggenheim Securities analyst Michael Schmidt ("Schmidt"):

> [SCHMIDT:] Maybe, Michael, first, could you help us and investors to understand this by providing maybe some more details? Maybe, first, could you confirm whether these CMC issues are exclusively related to your facility in Morris Plains?
>
> [PEHL:] Yes, Michael. Thanks for the question. So to start with, I have to say the CRL was clearly unexpected as we felt we had fully addressed all the open questions during our interactions with the agency.
>
> And what I want to make very clear is that we continue to believe that all the issues are fully addressable.

> To your question, the questions that we got, as I was just saying, are in relation to questions that we felt we have handled already. They are not clinical. They are not preclinical of nature. They don't required any new data generation, no tox. They are not [study] site related. They are not partner related. So they are obviously questions where we had a lot of interaction already.
>
> Once again, we feel they are fully addressable. Our next step, of course, is to interact with the agency to fully understand those, this is certainly a very fresh situation for us, and then come up with a very robust plan for the fastest resubmission possible.

126. As a result of the January 17 and January 18 disclosures, Immunomedics' share price on the Nasdaq fell to a close of $13.31 on January 18, 2018, or 26.4% from the prior day's closing of $18.09. This represented a one-day market capitalization loss of approximately $1 billion.

ADDITIONAL ALLEGATIONS OF SCIENTER

127. With a long history of operating losses and almost four decades of existence without successfully developing a drug that obtained FDA approval, Immunomedics finally had a chance at achieving success with IMMU-132. Realizing that they could not achieve this alone, Immunomedics entered into a $2 billion licensing agreement for IMMU-132 with Seattle Genetics, wherein Seattle Genetics would be responsible for conducting a Phase 3 clinical trial for IMMU-132, in addition to the manufacturing and commercializing IMMU-132. Seattle Genetics would pay Immunomedics $300 million upfront, with the balance paid upon achieving certain clinical, development, regulatory and sales milestones.

128. However, activist shareholder venBio believed Immunomedics was selling IMMU-132 at a steep discount and waged a successful proxy war resulting in the installation of venBio representatives Aghazadeh, Canute, Hutt and Islam on the Company's Board of Directors. At the same time, Rosenberg was hired to get the Morris Plains manufacturing plant ready for the FDA pre-approval inspection, and Pehl was hired as CEO based on his purported track record of successfully seeing drugs through FDA approval at Celgene.

129. After the collapse of the $2.0 billion Seattle Genetics deal, Immunomedics was faced with immense financial pressure. To raise funds, Defendants misled the public about the state of Immunomedics' BLA and failed to disclose the Data Integrity Breach. Based on these misrepresentations and material omissions, Defendants artificially inflated Immunomedics' stock price and, in June 2018, launched a follow-on offering of Immunomedics' common stock. Notably, the $300 million obtained from investors was to be used, in part, to correct the Data Integrity Breach and ready the Morris Plains manufacturing facility for the FDA pre-approval inspection. The total net proceeds from the June 2018 offering, including the underwriters' full exercise of the over-allotment option, was $300 million from the sale of 13.225 million shares of common stock at $24.00 per share.

130. But for Defendants' deliberate decision to withhold information related to the Data Integrity Breach, Immunomedics' Class Period stock price would have

been significantly lower, and the Company would not have been able to obtain the $300 million on the same terms and without significant additional dilution to Defendants, venBio and other current shareholders. Without the financing from the June 2018 offering, Immunomedics would not have had the funding to make manufacturing improvements and address the Data Integrity Breach, thereby impeding its ability to obtain FDA approval of its BLA and ultimate commercialization of IMMU-132.

LOSS CAUSATION/ECONOMIC LOSS

131. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive investors and the market and a course of conduct that artificially inflated the price of Immunomedics stock and operated as a fraud or deceit on Class Period purchasers of Immunomedics stock by misrepresenting and omitting material information about the Data Integrity Breach. When Defendants' prior misrepresentations and omissions were disclosed to the market, Immunomedics' stock price fell precipitously, as the prior artificial inflation came out of the price. As a result of their purchases of Immunomedics' stock during the Class Period, Lead Plaintiffs and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

132. Defendants' misleading statements and omissions of material facts, identified herein at ¶¶93-103, 106, 108-113, 115-120, had the intended effect and

caused Immunomedics' stock to trade at artificially inflated prices during the Class Period. As a direct result of the November 7, 2018, December 20, 2018 and January 18, 2019 disclosures, as detailed in **¶¶Error! Reference source not found.**-126, Immunomedics' stock price suffered significant declines.

133. The disclosure after the market closed on November 7, 2018, as detailed at **¶¶Error! Reference source not found.-Error! Reference source not found.**, had a direct impact on the Company's stock price. On November 8, 2018, the price of Immunomedics' stock fell more than 8%, from $24.24 per share at the close November 7, 2018, to close at $22.02 on November 8, 2018, in response to Defendants' vague warning about "issues" with the FDA

134. The disclosure before the market opened on December 20, 2018, as detailed in ¶¶122-123, also had a direct impact on Immunomedics' stock price. On December 20, 2018, the price of Immunomedics' stock dropped $4.86 per share during the first hours of trading on December 20, 2018, and even with Defendants' efforts to prop up the stock price with additional misleading statements, it was down $3.47 per share for the day. This represented a 20% drop in direct response to the disclosures regarding the Data Integrity Breach and the FDA's August 2018 pre-approval inspection.

135. The disclosures prior to the market opening on January 18, 2019, when Immunomedics announced that it had received a CRL from the FDA, as detailed

above in ¶¶124-126, also had a direct impact on the Company's stock price. The price of Immunomedics' stock fell 26.4% on January 18, 2019, from a closing price of $18.09 on January 17, 2019 to a close of $13.31 on January 18, 2019, as a direct result of receipt of the CRL and Defendants' explanations as to why the CRL had been issued by the FDA.

136. The declines in Immunomedics' stock price on November 7, 2018, December 20, 2018 and January 18, 2019 were a direct result of the nature and extent of Defendants' prior misstatements and omissions being revealed to investors and the market.

137. The timing and magnitude of Immunomedics' stock price decline negates any inference that the losses suffered by Lead Plaintiffs and other Class members was caused by changed market conditions, macroeconomic or industry factors or Company-specific factors unrelated to Defendants' fraudulent conduct. On November 8, 2018, Nasdaq was down only 0.5%, with the Nasdaq U.S. Smart Pharmaceuticals Index flat. On December 20, 2018, the Nasdaq declined 1.6% and the Nasdaq Smart Pharma Index declined 1.9%. And on January 18, 2019, when Immunomedics' stock fell by 26.4%, the Nasdaq and Nasdaq Smart Pharmaceuticals Index increased 1.0% and 0.6%, respectively.

138. The economic losses suffered by Lead Plaintiffs and other members of the Class were a direct result of Defendants' fraudulent scheme to inflate

Immunomedics' stock price and the subsequent, significant declines in the value of that stock when Defendants' prior misrepresentations and omissions were revealed.

COUNT I

For Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

139. Plaintiffs incorporate ¶¶1-138 by reference.

140. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and concealed material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

141. Defendants violated §10(b) of the Exchange Act and Rule 10b-5 in that they:

(a) Employed devices, schemes, and artifices to defraud;

(b) Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiffs and others similarly situated in connection with their purchases of Immunomedics securities during the Class Period.

142. In addition to the duties of full disclosure imposed on Defendants as a result of their affirmative false and misleading statements to the public, Defendants had a duty to promptly disseminate truthful information with respect to Immunomedics' operations and performance that would be material to investors in compliance with the integrated disclosure provisions of the SEC, including with respect to the Company's revenue and earnings trends, so that the market prices of the Company's securities would be based on truthful, complete, and accurate information. SEC Regulations S-X (17 C.F.R. §210.01, *et seq*.) and S-K (17 C.F.R. §229.10, *et seq*.).

143. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the Class have suffered damages in connection with their respective purchases of Immunomedics common stock during the Class Period, because, in reliance on the integrity of the market, they paid artificially inflated prices for Immunomedics securities and experienced losses when the artificial inflation was released from Immunomedics securities as a result of the revelations and prices decline detailed herein. Plaintiffs and the Class would not have purchased Immunomedics securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

144. By virtue of the foregoing, Immunomedics and the Exchange Act Defendants have each violated §10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

COUNT II

For Violations of Section 20(a) of the Exchange Act Against All Defendants

145. Plaintiffs incorporate ¶¶1-144 by reference.

146. The Individual Defendants acted as controlling persons of Immunomedics within the meaning of §20(a) of the Exchange Act. Immunomedics controlled all of its employees and the Individual Defendants. By virtue of their high-level positions, and their ownership and contractual rights, and awareness of the operational status of the Morris Plains manufacturing facility, as well as their intimate knowledge of the false statements and omissions made by the Company and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the Company's decision-making, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. The Individual Defendants participated in the conference calls with investors and analysts, described herein at ¶¶94-96, 98-99, 108, 113, 115-120, and/or prepared and approved the Company's SEC filings and press releases, described herein at ¶¶93, 97, 100-103, 106, 109-112, alleged by Plaintiffs to be misleading.

147. In particular, Defendants had direct and supervisory involvement in the Company's day-to-day operations and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same. By reason of such conduct, Defendants are liable pursuant to §20(a).

148. As set forth above, Defendants each violated §10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, Defendants are liable pursuant to §20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of Immunomedics common stock during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for relief and judgment, as follows:

A. Determining that this action is a proper class action, and certifying Plaintiffs as Class representatives under Federal Rule of Civil Procedure 23 and Plaintiffs' counsel as Class counsel;

B. Awarding compensatory damages in favor of Plaintiffs and the other members of the Class against all Defendants, jointly and severally, for all damages

sustained as a result of Defendants' violations of the federal securities laws, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such equitable, injunctive or other and further relief as the Court may deem just and proper, including, but not limited to, rescission.

JURY DEMAND

Plaintiffs hereby demand a trial by jury.

DATED: July 19, 2021

/s/ James E. Cecchi

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